ATTACHMENT 2

JUN 2 6 2014

PONTiS™

ORTHOPAEDICS

510(k) Summary

Owner's Name	Leonard Gordon
Submitter Address	2299 Post Street Suite 107 San Francisco, CA 94115
Phone Number	(415) 567-8935
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510(k) Owner	PONTiS Orthopaedics, LLC
Contact Person	Leonard Gordon
Date Prepared	April 22, 2014
Trade Name	Multifilament Stainless Steel Suture with Crimp
Common name	Stainless Steel Suture
Classification Name	Smooth or Threaded Metallic Bone Fixation Fastener
Section	§ CFR 888.3040
Product Code	Primary - MBI
Predicate Device(s)	Mitek G11 Quick Anchor Plus - K041115 Arthrex Swivelock - K101823 Smith and Nephew Endobutton - K081098 PONTiS Orthopaedics ferroFIBRE™ - K081060 Pioneer Surgical Technologies SilCoat Sternal Cable – K993286
Device Description	Multifilament stainless steel sutures with crimps are intended for use in soft tissue to bone and bone to bone approximation and fixation during orthopedic procedures in the elbow, foot, ankle, knee, shoulder, and wrist for indications such as: Elbow – biceps tendon attachment; Foot and Ankle – achilles tendon attachment; Knee – patella tendon attachment to bone; Shoulder –biceps tendon tenodesis; Wrist – scapho-lunate approximation. Multifilament Stainless Steel Sutures with Crimps are available in a range of USP sizes (4-0 to #3) and lengths, attached to stainless steel needles of various types and sizes. Multifilament SS Sutures are manufactured in 1X19, 7X7 or 7X19 filament constructions. The sutures are identified by black and white tips which are used as a guide at the tip, and are removed prior to the end of the procedure. The sutures and tips were cleared for use under the PONTiS 510(k), K101126.

	The washer is available in the following sizes: 000-0739_1-01 Washer, Plate – 0.012", .045" 000-0739_1-00 Washer, Plate – 0.012", .062" 000-0764 Washer, Plate, 2-Hole – 0.012" The suture guide and the cannulated K-wire are available in one size.
Reason for 510(k)	New Device
Indications for Use	Multifilament stainless steel sutures with crimps are intended for use in soft tissue to bone and bone to bone approximation and fixation during orthopedic procedures in the elbow, foot, ankle, knee, shoulder, and wrist for indications such as: Elbow – biceps tendon attachment; Foot and Ankle – achilles tendon attachment; Knee – patella tendon attachment to bone; Shoulder –biceps tendon tenodesis; Wrist – scapho-lunate approximation.
Technological Characteristics	The Multifilament stainless steel suture is the same suture as was cleared under K081060. Each suture size and number of suture strands will require a different crimp size. All biocompatibility testing performed, which was conducted under the predicate submission K081060 remain applicable for this submission as the materials are the same. This indicates that the components are safe for their intended use. The PONTiS Multifilament Stainless Steel Suture with Crimps is a single use, sterile implantable device, sterilized by ethylene oxide. The predicate devices are single use, sterile implantable device, sterilized by gamma irradiation and ethylene oxide.
Substantial Equivalence	The Multifilament Stainless Steel Suture with Crimps is substantially equivalent in design, manufacturing materials, intended use, principles of operation, and technical characteristics to the predicates. The risk analysis performed, raised no new issues of safety or effectiveness.
Nonclinical Tests Performed	The verification and validation testing of the Multifilament Stainless Steel Suture with Crimps included knot failure force compared to crimp failure force, pull out strength, attachment strength, static testing and ultimate load following cyclic loading. Bench testing demonstrated that the mechanical properties are substantially equivalent for tendon to bone and bone to bone approximation.
Conclusions Drawn	Bases on the indications for use, technological characteristics and performance test results, the Multifilament Stainless Steel Suture with Crimp is substantially equivalent to the predicate.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

June 26, 2014

PONTiS Orthopaedics LLC
Leonard Gordon, M.D.
President
2229 Post Street, Suite 103
San Francisco, California 94115

Re: K133579
Trade/Device Name: Multifilament Stainless Steel Sutures with Crimps
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: Class II
Product Code: MBI
Dated: May 19, 2014
Received: May 20, 2014

Dear Dr. Gordon:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Lori A. Wiggins

for
Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

ATTACHMENT 1

Statement of Indications for Use

510(k) Number: K133579

Manufacturer: PONTiS Orthopaedics, LLC

Device Name: Multifilament Stainless Steel Sutures with Crimps

Indications for Use:

Multifilament stainless steel sutures with crimps are intended for use in soft tissue to bone and bone to bone approximation and fixation during orthopedic procedures in the elbow, foot, ankle, knee, shoulder, and wrist for indications such as: Elbow – biceps tendon attachment; Foot and Ankle – achilles tendon attachment; Knee – patella tendon attachment to bone; Shoulder –biceps tendon tenodesis; Wrist – scapho-lunate approximation.

Prescription Use (21 CFR Part 801 Subpart D)	XX	AND/OR	Over the Counter Use (21 CFR Part 801 Subpart C)	__

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Exemption (ODE)

Casey L. Hanley, Ph.D.

Division of Orthopedic Devices